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15 510(k) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Per 21 CFR 807.92)

General Company Information

Name: Endoventions
Contact: Don Canal
Vice President RA/QA

Address: 9013 Perimeter Woods, Suite A
Charlotte, NC 28216

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Date Prepared: June 17, 2005

General Device Information

Product Name: ALIMAXX-E™ Esophageal Stent System
Classification: "Esophageal Prosthesis", Product code: ESW
21 CFR 878.3610 - Class II

Predicate Devices

Boston Scientific Corp. Inc. Ultraflex™ Esophageal NG Stent System [501(k) Number K032930]

Rusch International Polyflex Stent for the Esophagus with Introducer / Delivery System [510(k) Number K030559]

Description

The Endoventions Esophageal Stent Technology System is comprised of two components: the stent and the delivery system. The nitinol stent is completely covered with a biocompatible polyurethane (ChronoFlex™) membrane and is self-expanding. The stent expansion results from the mechanical properties of the metal and the proprietary geometry. The stent is designed with a larger diameter

near the distal and proximal ends to minimize the possibility of migration. The overall stent geometry is designed to maintain a constant length over the entire range of possible diameters. As a result of this unique design the stent has virtually no foreshortening, thus facilitating the selection of the appropriate stent length.

Intended Use (Indications)

The Endoventions ALIMAXX-E™ Esophageal Stent System is intended for maintaining esophageal lumen patency in esophageal strictures caused by intrinsic and / or extrinsic malignant tumors. The stent is also indicated for occlusion of esophageal fistulae.

Substantial Equivalence

This Notice supports the position that the Endoventions Esophageal Stent is substantially equivalent to a number of previously cleared devices, including the Boston Scientific Corp. Inc. Ultraflex™ Esophageal NG Stent System [501(k) Number K032930] and the Rusch International Polyflex Stent for the Esophagus with Introducer / Delivery System [510(k) Number K030559].

The 510(k) Notice contains summaries of physical test results, and biocompatibility test results as specified in the FDA Guidance Document for Testing Esophageal and Tracheal Prostheses (April 28, 1998).

The data presented demonstrate that the device is biocompatible and is suitable for its indicated use.

The single-patient-use components of the ALIMAXX-E™ Esophageal Stent System are provided non-sterile.

Conclusions

Endoventions believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Endoventions Esophageal Stent. The materials from which the Endoventions device is fabricated have an established history of use in clinical applications, and the devices produced by Endoventions have been tested in accordance with applicable FDA guidelines.



JUL 11 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Mr. Donald V. Canal
Vice President RA/QA
Endoventions
9013 Perimeter Woods, Suite A
CHARLOTTE NC 28216

Re: K051621

Trade/Device Name: Endoventions™ ALIMAXX-E™ Esophageal Stent System

Regulation Number: 21 CFR §878.3610

Regulation Name: Esophageal prosthesis

Regulatory Class: II

Product Code: ESW

Dated: June 17, 2005

Received: June 21, 2005

Dear Mr. Canal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

12 INTENDED USE STATEMENT

Device Name: Endoventions, ALIMAXX-E™ Esophageal Stent System

Indications For Use:

The Endoventions ALIMAXX-E™ Esophageal Stent System is intended for maintaining esophageal lumen patency in esophageal strictures caused by intrinsic and / or extrinsic malignant tumors. The stent is also indicated for occlusion of esophageal fistulae.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
SIO(k) Number K051621